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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,494	04/18/2000	Frank Meulewacter	021565-075	2755
21839	7590	03/30/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404				MEHTA, ASHWIN D
		ART UNIT		PAPER NUMBER
		1638		

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/551,494	MEULEWAETER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Ashwin Mehta	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32,38-43 and 49-60 is/are pending in the application.
- 4a) Of the above claim(s) 53,55-57,59 and 60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32,38-43,49-52,54 and 58 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 April 2000 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

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**DETAILED ACTION**

1. The examination of this application has been transferred to Examiner Ashwin Mehta, Art Unit 1638.
2. The rejection of claims 32, 34, 38, 42, 43, 45, and 49 under 35 U.S.C. 103(a) is withdrawn, in light of the claim amendments.

*Election/Restrictions*

3. Applicant's election with traverse of Group II, claims 54 and 58, and SEQ ID NO: 5, in the reply filed on October 7, 2004 to the supplemental restriction requirement, is acknowledged. The traversal is on the ground(s) that the recited RNA sequences were within the scope of generic claim 32, the origin of assembly of tobacco mosaic virus (response, page 1, 2<sup>nd</sup> full paragraph). This is not found persuasive because the claims are directed to distinct sequences, from distinct viral strains.

The requirement is still deemed proper and is therefore made FINAL. Non-elected claims 53, 55, 56, 57, 59, and 60 are withdrawn from consideration. Claims 32, 38-43, 49-52, 54, and 58 are examined in this Office action.

*Claim Objections*

4. Claim 42 is objected to for being dependent upon non-elected claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32, 38-43, 49-52, 54, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 32, 39, 43, and 50: the recitation, “a chimeric nucleic acid which when transcribed yields said inhibitory RNA” renders the claims indefinite. It is unclear exactly what is meant by “chimeric nucleic acid.” What does this nucleic acid consist of?

Further in claims 32, 39, 43, and 50: the recitation “inhibitory RNA” renders the claims indefinite. The specification on page 9 indicates that inhibitory RNA is “preferably sense or antisense RNA, particularly inhibitory RNA comprising an inverted repeat, especially comprising an inverted repeat, especially inhibitory RNA comprising a complementary stretch of at least 50, preferably at least 100 nucleotides of sense and antisense RNA”. However, the term, “preferably” is “open” language that does not exclude other structures that can be considered inhibitory RNA. It is unclear what other structures can be considered to be “inhibitory RNA”. The claims are also indefinite because they do not indicate what the inhibitory RNA is intended to inhibit.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 32, 38, 42, 43, 49, 54, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method for introducing inhibitory RNA in the cytoplasm of plant cells, comprising introducing into said cell a viral RNA vector derived from satellite tobacco mosaic virus, said vector comprising said inhibitory RNA or a chimeric nucleic acid which when transcribed yields said inhibitory RNA, and an origin of assembly of tobacco mosaic virus, wherein all or part of the coat protein gene of the satellite TMV has been deleted; and introducing a corresponding helper virus; or said method wherein the viral vector is derived from satellite tobacco necrosis virus, and can comprise the full coat protein gene; a kit for introduction of inhibitory RNA in the cytoplasm of a plant cell.

The method of claim 32 broadly encompasses introducing a viral RNA vector into plant cells, wherein the vector is derived from the genome of satellite tobacco mosaic virus, comprises inhibitory RNA, an origin of assembly of tobacco mosaic virus, and wherein part or all of the coat protein gene of said satellite tobacco mosaic virus has been deleted. Claim 43 is directed to a kit comprising said viral RNA vector. The inhibitory RNA of the vectors causes gene silencing of a target gene in a host plant cell when the vectors are introduced into the plant cell along with a corresponding helper virus that proteins necessary for movement and replication *in trans*.

However, the specification does not enable the claimed methods or kits when the vector comprises deletions of the coat protein-coding region of the satellite virus. Gossele et al. (Plant

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J., 2002, Vol. 32, pages 859-866) also teach the development of this system to cause gene silencing of target genes in plant cells. Gossele et al. teach that vectors derived from satellite tobacco mosaic virus that comprised deletions of the coat protein gene of the satellite virus did not result in gene silencing of the target gene, and that only a vector containing a frameshift mutation in the coat protein gene caused silencing of the target pds gene in host tobacco leaves (page 860). In the absence of further guidance, undue experimentation would be required by one skilled in the art to use the claimed vectors comprising a deletion of part or the entire coat protein gene of the satellite virus. Given the breadth of the claims comprising viral RNA vectors derived from satellite tobacco mosaic virus wherein part or all of the coat protein encoding gene is deleted, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

7. Claims 32, 38-43, 49-52, 54, and 58 are rejected. Non-elected claims 53, 55, 56, 57, 59, and 60 are withdrawn from consideration.

#### *Contact Information*

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

March 18, 2005



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638